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RD

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/422,838	10/22/99	LIU	C 01017/36263

HM12/0326
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EXAMINER

ZHOU, S

ART UNIT	PAPER NUMBER
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1631

DATE MAILED:

2
03/26/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/422,838

Applicant(s)

LIU ET AL.

Examiner

Shubo "Joe" Zhou

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claims 1-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) ____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☒ Other: *Raw Sequence Listing Error Report*.

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR § 1.821 through 1.825 because the computer readable form of the Sequence Listing is defective (see the enclosed Raw Sequence Listing Error Report). Applicants are given the same response time regarding this failure to comply as that set forth to respond to this office action. A complete response to this office action includes compliance with this sequence rule compliance. Failure to comply may result in abandonment of this application.

Restriction/Election Requirement

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 1-16, 24, and 27, drawn to peptide compounds, classified in Class 530, subclass 300. If this group is elected, then the below summarized species election requirement also is required.
- II. Claims 17-23, drawn to peptide compounds, classified in Class 435, subclass 300. If this group is elected, then the below summarized species election requirement also is required.
- III. Claims 25-26, drawn to a method of increasing megakaryocytes or platelets using peptide compounds, classified in Class 435, subclass 7.1. If this group is elected, then the below summarized species election requirement also is required.
- IV. Claims 28-33, drawn to polynucleotides, classified in Class 536, subclass

23.1. If this group is elected, then the below summarized species election requirement also is required.

V. Claim 34, drawn to a method of producing a peptide compound, classified in Class 435, subclass 69.2. If this group is elected, then the below summarized species election requirement also is required.

The inventions are independent/distinct, each from the other because of the following reasons:

The inventions of Groups (I-III, and V) and Group IV are independent distinct inventions because they are directed to different chemical types regarding the critical limitations therein. For Groups (I-III, and V), the critical feature is peptide; for Group IV, the critical feature is a nucleic acid. It is acknowledged that various processing steps may cause a polypeptide of Groups (I-III, and V) to be directed as to its synthesis by a polynucleotide of Group IV, however, the completely separate chemical types of the inventions of the nucleic acid and polypeptide supports the undue search burden if they were examined together. Additionally, polynucleotides and polypeptides have been most commonly, albeit not always, separately characterized and published in the biochemical literature, thus significantly adding to the search burden if examined together as compared to being searched separately. Also, it is pointed out that processing that may connect two Groups does not prevent them from being viewed as distinct because enough processing can result in producing any composition from any other composition if the processing is not limited as to additions, subtractions, enzyme action, etc. Thus, the two Groupings of (I-III, and V) and IV are independent and/or distinct invention types for restriction purposes.

The inventions of Groups I and II are related but distinct products. Group I is drawn to peptides having a general structural formula as shown in the instant claim 1, and Group II is drawn to peptides having a general structural formula as shown in the instant claim 17. These two different types of compounds clearly have different structure, usually different functions and are usually published separately in the literature. Thus, it would be an undue search burden for them to be examined together.

The inventions of Groups (I-II) and Group III are related as product and distinct process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the peptides of Groups (I-II) can be used in the process of the invention of Group III which is directed to treatment. Alternatively, the peptides can be used to generate antibodies which is another distinct use of the peptides.

The inventions of Groups (I-II) and Group V are related as product and distinct process of making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process as claimed can be used to make other and materially different product or (2) the product as claimed can be made by another and materially different process (MPEP §806.05(f)). In the instant case, the peptides of Groups (I-II) can be produced by the process of invention of Group V. Alternatively, the polypeptides can be produced by a distinct *in vitro* chemical synthetic process.

Additional Specie election regarding all the Groups above

It is noted that some claims in the instant application contain multiple species of inventions which require restriction/election.

Claims in Group I are directed to peptide compounds with a general structure as shown in the instant claim 1, wherein, TMP1 and TMP2 have different X #, and L1 has different components; peptides are linear or cyclic, and they are monomeric or dimeric. These different variables are considered as species subject matter. These different species render different structure and often different functions, and, therefore, are usually published separately and require different searches. Applicant is required to elect only one species for the claimed invention of Group I for the purpose of examination. A species is a compound with the structure formula as shown in claim 1 with the following: (1) TMP1 and TMP1 having a particular length of sequence (i.e. number of Xs); (2) each X# having one particular amino acid residue; (3) L1 having a particular residue or sequence of residues; (4) TMP1 and/or TMP2 are derivatized in a particular way; (5) all the amino acid having a particular configuration, e.g. D configuration; (6) the peptide compound either being linear or having cyclic structure and (7) the peptide compound either being monomeric or dimeric. Applicant is required to elect a particular for each of the above 7 types of particulars for the species elected.

Similarly, the claims in Group II are directed to peptide compounds with a general structure as shown in the instant claim 17, wherein, there are different variables: TMP1, TMP2, Fc, L1, L2, L3, etc. Also, the peptides could be linear or cyclic, monomeric or dimeric. These variables are considered as species subject matter. These different species render different structure and often different functions, and, therefore, are usually published separately and require different searches. Applicant is required to elect only one species for the claimed invention of Groups IV-V for the purpose of examination. A species is a compound with the structure formula as shown in claim 17 with the following: (1) TMP1 and TMP1 having a particular length of sequence (i.e. number of Xs); (2) each X# having one particular amino acid residue; (3)

L1 or L2 or L3 having a particular residue or sequence of residues, i.e. with a particular n number or q number or r number; (4) TMP1 and/or TMP2 are derivatized in a particular way; (5) Fc having a particular sequence, also with a particular m number or p number; and (6) all the amino acid having a particular configuration, e.g. D configuration; (7) the peptide compound either being linear or having cyclic structure and (8) the peptide compound either being monomeric or dimeric. Applicant is required to elect a particular for each of the above 8 types of particulars for the species elected.

Also, the claims in Group IV are directed to different polynucleotides encoding different peptide compounds as claimed in the other Groups of the instant application. These different polynucleotide are considered as species subject matter. These different species render different structure and often different functions, and, therefore, are usually published separately and require different searches. Applicant is required to elect only one species for the claimed invention of Group IV for the purpose of examination. A species is a polynucleotide encoding a particular species of peptide compound as set forth above in the other Groups.

Additionally, the claims in Group V are directed to methods of producing different peptide compounds as set forth above. These methods of producing different peptide compounds are considered as species subject matter. These different species require different procedures and/or reagents and produce different results, and, therefore, are usually published separately and require different searches. Applicant is required to elect only one species for the claimed invention of Group V for the purpose of examination. A species is a method only producing a particular species of peptide compound as set forth above in the other Groups.

Because these inventions are independent/distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Applicant is further reminded that a fully responsive communication will comprise a proper election of a Group and species, as well as compliance with the sequence rules as set forth above.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to:

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Art Unit: 1631

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Shubo "Joe" Zhou, Ph.D., whose telephone number is (703) 605-1158. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technical Center receptionist whose telephone number is (703) 308-0196.

S. "Joe" Zhou: sjz

Patent Examiner

March 22, 2001


ARDIN H. MARSCHEL
PRIMARY EXAMINER